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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,485	11/07/2007	Jacob M. Waugh	13720-105074US1	1919
65989	7590	04/05/2010	EXAMINER	
KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			04/05/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/591,485	WAUGH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	SAMUEL LIU	1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 November 2007.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 78-80, 84, 85, 88 and 90-97 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 78-80, 84, 85, 88 and 90-97 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### *Status of claims*

Claims 78-80, 84, 85, 88 and 90- 97 are pending.

The preliminary amendment filed 11/7/07 which cancels claims 1-77, 81-83, 86, 87, 89 and 98-240, and amends claims 78-80, 84, 85, 88 and 90-97 has been entered.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 91-94, 96 and 97, drawn to a method of providing an aesthetic effect to a subject in need thereof comprising administering to the subject in need thereof a botulinum toxin (BT).

Group II, claims 91-94, 96 and 97, drawn to a method of providing an cosmetic effect to a subject in need thereof comprising administering to the subject in need thereof a botulinum toxin (BT).

Group III, claims 91-93 and 95-97, drawn to a method of reducing a symptoms associated with muscle spasm or cramping comprising administering to the subject in need thereof comprising administering to the subject a botulinum toxin (BT).

The inventions listed as Groups 1-4 do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Instant method of claims is obvious over Rothbard et al. (WO0162297). This patent teaches a method of transdermally (patent claims 1, 21 and 25) delivering to a subject a

composition comprising a biological compound, e.g., antibacterials, antivirals or/and hormone (patent claim 20) with a delivery-enhancing transportor, e.g., positively charged arginine (patent claims 1, 7 and 10). This teaches instant claims 78-80 and 84; and thus, these claims are not considered to “link” Groups I, II and III. Therefore, the claimed method (linking claims) at least does not constitute a special technical feature as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

*Linking claim practice*

Upon further consideration and to clarify election for the transformed host cell, the following section is applicable to the above pending claims.

Claims 78-80, 84, 85, 88 and 90 link Inventions I, II and III, wherein the transdermal administration of the biologically active protein with the positively charged carrier molecule is required for each Group of the Inventions thereof.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 78-80, 84, 85, 88 and 90. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. Herein, in order to avoid the additional election for the host cell ending up being drawn into election of more than one species, the above linking claims pursuant to the restriction purpose for the current invention is deemed proper.

*Additional Election*

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed biomolecule to which claims are restricted. The response to the election requirement should also identify the claims readable thereon as directed to the elected invention. If Group 1 or 2 or 3 is elected, applicants are required to elect: one particular type of botulinum toxin (BT) from claim 91 because BT types A through G (A, B, C, D, E, F and G) are distinct in structure and/or function (see [0003], US 20040265935).

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121, since patient populations for the claimed methods using the different type of BT differ from one another. This is evidenced by that the BT types A, B, E, and F cause botulism in humans while BT types C and D cause botulism in other mammals and bird (see [0003], US 20040265935).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Liu whose telephone number is (571)272-0949. The examiner can normally be reached on Monday-Friday, 9 am to 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Wei Liu/  
Patent Examiner, Art Unit 1656

/ANAND U DESAI/  
Primary Examiner, Art Unit 1656

February 11, 2010